

510(k) SUMMARY

K071421

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Submitter Name: Promepla  
Submitter Address: 9 Avenue Prince Albert II  
Monaco 98000  
Contact Person: Patsy Trisler, J.D., RAC (US Agent)  
Phone Number: 301-652-5344  
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Date Prepared: September 6, 2007

**OCT 4<sup>th</sup> 2007**

Device Trade Name: Intravascular Administration Set and Extension Set  
Device Common Name: Intravascular Administration Set  
Classification Number: 21 CFR 880.5440  
Classification Name: Set, Administration, Intravascular  
Product Code: FPA

Predicate Devices: K051499, Intravascular Administration Set and Extension Set, Medegen Medical Manufacturing Services  
K970255, KippMed I.V. Manifold, The Kipp Group

Statement of Intended Use: The Intravascular Administration Set and Extension Set is a device used to administer fluids from a container to a patient's vascular system through a needle or catheter inserted into the patient's artery or vein. The Administration Set is also intended for use with a peristaltic pump for IV purposes only.

Device Description: The Promepla Intravascular administration and extension sets contain components that are commonly found in this category of IV sets.

The IV Administration (pump tube) Set belongs to a full line of intravenous fluid delivery sets. It is an infusion set intended to deliver fluids, medications, blood and blood products, using continuous or intermittent delivery through clinically acceptable routes of administration (e.g. intravenous, intra-arterial, subcutaneous, epidural, enteral or irrigation of fluid spaces). An optional component, a flow controller allows the use with a peristaltic pump.

The Extension Set device is a triple lumen peripheral set with two detachable long lines, belonging to a family of extension tubing sets. This device uses a main gravity drip line, plus the two long extension limbs. It is a connector system, which has anti free-flow valves and line clamps, which are common in intravascular extension sets on the market. The extension set allows IV fluids to be given simultaneously by way of the same connector.

Both the IV Administration Set and Extension Set are provided sterile (by EtO) and are for single use only. They are intended only for use by trained professionals in a clinic or hospital environment.

Comparison to the Predicate Devices: Based upon the intended use, design, materials, and the testing conducted, it can be concluded the Promepla Intravascular Administration Set and Extension Set are substantially equivalent to the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Promepla  
C/O Ms. Patsy J. Trisler, J.D., RAC  
Regulatory Consultant and US Agent  
5600 Wisconsin Avenue, Suite 509  
Chevy Chase, Maryland 20815

OCT 4 2007

Re: K071421

Trade/Device Name: Promepla Intravascular Administration Set and Extension Set  
Regulation Number: 21 CFR 880.5440  
Regulation Name: Intravascular Administration Set  
Regulatory Class: II  
Product Code: FPA  
Dated: September 6, 2007  
Received: September 10, 2007

Dear Ms. Trisler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Chiu Lin", with a stylized flourish at the end.

Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

510(k) Number (if known): K071421

Device Name: Promepla Intravascular Administration Set and Extension Set

**Indications for Use:**

The Intravascular Administration Set and Extension Set is a device used to administer fluids from a container to a patient's vascular system through a needle or catheter inserted into the patient's artery or vein. The Administration Set is also intended for use with a peristaltic pump for IV purposes only.

Prescription Use   x    
(Part 21 CFR 801 Subpart D)

AND/OR


Over-The-Counter Use             
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE  
OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

*(Posted November 13, 2003)*

  
(Division Sign-Off)  
Division of Anesthesiology, General Hospital  
Infection Control, Dental Devices

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